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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,026	08/18/2003	Steven Vanhamel	ATMI-624	3218
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ATMI, INC.			BRUENJES, CHRISTOPHER P	
7 COMMERCE DRIVE			ART UNIT	PAPER NUMBER
DANBURY, CT 06810			1772	

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,026

Applicant(s)

VANHAMEL ET AL.

Examiner

Christopher P Bruenjes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 50-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20050121.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-49 in the reply filed on December 27, 2004 is acknowledged. The traversal is on the ground(s) that the respective groups of claims are related and interdependent. This is not found persuasive because structure alone and not the process of making or using the article limit article claims. In this case, the article claimed is a packaging article or multilayer web comprising a first layer of a porous material and a second layer of a non-porous material comprising a peelable film that bonds the second layer to the first layer. The article will have the same structure regardless of whether an integrity testing method is performed on the structure during or after manufacture. Therefore, to produce and use the article claimed in claims 1-49 a step of pressurizing said packaging article and a step of exposing said packaging article to a sterilant gas is not required because the article would have the same structure regardless of these two steps. Furthermore, the articles claims merely limit the article to being able to perform the function of peel removal of the second layer from the first layer to expose the first layer of porous material for passage of gas

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therethrough, the article claims do not claim that the process is performed in the form of a method claim. Thus, although Groups I and II are related in that the article could be produced or used in the manner taught in the method of claims 50-79, the article does not have to be produced or used in that manner and still meet all the limitations of claims 1-49.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 50-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 27, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11, 31, 41-42, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 11, 31, 42, and 47, the trademark TYVEK should not be used in the claims because a trademark or trade name is used to identify a source of goods and not the goods themselves. See MPEP 2173.05(u). Therefore, the word "TYVEK" in the claims should be deleted and replaced with the actual definition of the composition that "TYVEK" is being used to represent.

Regarding claims 41-42, there is a lack of antecedent basis for "said non-porous structural component" in line 2 of claim 41 and line 1 of claim 42. Based on the specification and the claim language surrounding claims 41 and 42, the examiner has determined that the limitation "said non-porous structural component" was meant to refer to "said sheet form structural component" of claim 22. If this determination is correct the claims should be amended respectively. If this determination is incorrect then there is no antecedent basis for "said peelable film" in line 2 of claim 42, which is referring to the peelable film of claim 22, which is part of the sheet form structural component.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 5-6, 10, 12-22, 25-26, 30, 32-41, and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirsch et al (USPN 4,055,672).

Hirsch et al anticipate a multilayer web material (reference number 14, Figure 1 or reference number 42, Figure 3) comprising a first layer of a porous material (reference number 22, Figure 1 or reference number 46, Figure 3) and a second layer (reference number 24, Figure 1 or reference number 48, Figure 3). The second layer is overlying and sealed to the first layer via a peelable adhesive (reference number 26, Figure 1 or reference number 50, Figure 3). The second layer is non-porous to passage of gas therethrough and comprises a peelable film in contact with the first layer of porous material, and the peelable film permits the peel removal of the second layer from the first layer to expose the first layer of porous material for passage of gas therethrough (see abstract). Regarding claim 22, Hirsch et al teach that the multilayer web material is a lid

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component of a packaging article. The limitation "useful for pressurization integrity testing and after pressurization integrity testing being permeable to sterilant gas for sterile packaging of a product article disposed therein" receives little patentable weight because it is a functional limitation in an article claim. Although every limitation is given consideration, articles are defined by what the article is, not what the article does. See MPEP 2114. In this case, Hirsch et al anticipate the structural limitations of claim 22 and the packaging article is capable of being used for the same purpose claimed in claim 22 because it has a permeable layer and a peel removable impermeable layer overlying and sealed to the permeable layer for removal to expose the permeable layer to passage of gas. Regarding claims 2, 5-6, 10, 25-26, and 30, Hirsch et al teach that the first layer comprises polyethylene (col.4, 1.34-43). Regarding claims 12-16 and 32-36, Hirsch et al teach that the second layer is comprised of impermeable materials such as polyester, nylon, cellophane, polypropylene, polyvinyl acetate, or saran in combination with polyethylene (col.4, 1.56-65), in which the composite of a layer and polyethylene anticipates the peelable film comprising a polyethylene and the second layer further comprising a back layer made of polyethylene. Regarding claims 17-18 and 37-41,

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Hirsch et al teaches that the multilayer web in one embodiment is a lid material for a tray package, in which the tray is formed of a non-porous structural component (reference number 12, Figure 1) in the form of a sheet or shaped member (Figure 1) and in a second embodiment the multilayer web is a wall or structural component of a bag adapted to hold a product article therein (col.3, 1.10-13 and Figure 3). Regarding claims 19-21 and 43-46, the limitations regarding the properties and type of product article packaged in the multilayer web article receives little patentable weight, because they are intended use limitations. Articles are defined by what the article is, not what the article does. In this case, the article of Hirsch et al based on the structure of the article would be capable of being used to package an article that must be sterile, a medical device, or pharmaceutical agent, and therefore Hirsch et al anticipate claims 19-21 and 43-46.

5. Claims 1-2, 5-22, 25-36, 40, and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (USPN 5,418,022).

Anderson et al anticipate a multilayer web material (reference number 10, Figure 1) comprising a first layer of a porous material (reference number 12, Figure 1) and a second

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layer (reference number 20, Figure 1). The second layer is overlying and sealed to the first layer via a peelable seal (reference number 30, Figure 1). The second layer is non-porous to passage of gas therethrough and comprises a peelable film in contact with the first layer of porous material, and the peelable film permits the peel removal of the second layer from the first layer to expose the first layer of porous material for passage of gas therethrough, because when the second layer is removed the first layer would be exposed from the direction the second layer was overlying (see abstract). Regarding claim 22, Hirsch et al teach that the multilayer web material is a lid component of a packaging article. The limitation "useful for pressurization integrity testing and after pressurization integrity testing being permeable to sterilant gas for sterile packaging of a product article disposed therein" receives little patentable weight because it is a functional limitation in an article claim. Although every limitation is given consideration, articles are defined by what the article is, not what the article does. See MPEP 2114. In this case, Anderson et al anticipate the structural limitations of claim 22 and the packaging article is capable of being used for the same purpose claimed in claim 22 because it has a permeable layer and a peel removable impermeable layer overlying and sealed to the

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permeable layer for removal to expose the permeable layer to passage of gas regardless of whether the permeable layer could be exposed to the passage of gas without removing the impermeable layer. Regarding claims 2, 5-11 and 25-31, Anderson et al teach that the first layer comprises TYVEK spunbonded olefin (col.2, 1.57-63) and teaches that TYVEK is spunbonded olefin sheet of high density polyethylene fibers formed by flash spinning continuous strands of ultrafine interconnected fibers, dispersing them onto a moving belt and then bonding them together with heat and pressure into a multi-layer sheet (col.1, 1.15-25). Regarding claims 12-16 and 32-36, Anderson et al teach that the second layer comprises a transparent polymeric material such as polyethylene film or laminates of polyethylene and polyester films (col.2, 1.5-15), therefore Anderson et al anticipates the peelable film comprising polyethylene in some embodiments and in the composite embodiment the second layer further contains a backing material comprising polyethylene. Regarding claims 17-18 and 40, Anderson et al teach the multilayer web article is incorporated in packaging as a structural component thereof as being the entire package, and because the structure of a bag is merely a container of flexible material for containing items the article of Anderson et al anticipates claims 18 and 40. Regarding claims 19-21 and 43-46,

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the limitations regarding the properties and type of product article packaged in the multilayer web article receives little patentable weight, because they are intended use limitations. Articles are defined by what the article is, not what the article does. In this case, the article of Anderson et al explicitly teaches that the package is used to package an article that must be sterile and a medical device (see abstract) and based on the structure of the article would be capable of being used to package a pharmaceutical agent, and therefore Anderson et al anticipate claims 19-21 and 43-46.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 3-4 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al (USPN 4,055,672) in view of Brown et al (USPN 5,217,772).

Hirsch et al teach all that is claimed in claims 2 and 22 as shown above, but fails to explicitly teach the first layer being formed of a cellulosic material such as paper. However, Hirsch et al teach that the first layer is formed of any gas permeable material having a suitable gas transmission rate of types which are well known in the art (col.4, l.34-44). Brown et al teach that well known permeable materials having a suitable gas transmission rate while remaining impermeable to bacteria and microorganisms, which would be a concern in food packaging, include fibrous layers (col.1, l.10-26). In particular, TYVEK and paper, which is a cellulosic material, are well known fibrous layers that meet the requirements of the gas permeable material used in Hirsch et al while remaining impermeable to bacteria and microorganisms. One of ordinary skill in the art would have recognized that Hirsch et al and Brown et al are analogous art insofar as both references are

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concerned with using combinations of permeable and non-permeable layers to preserve easily contaminated products during storage and transportation of the products within the packages.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to substitute the cellulosic paper gas permeable layer of Brown et al for the gas permeable layer of Hirsch et al because paper is a well known material used in the formation of gas permeable layers within peelable packages, and one of ordinary skill in the art would have selected the appropriate gas permeable layer from well-known gas permeable layers depending on the intended end result of the product, as taught by Hirsch et al. Specifically, one of ordinary skill in the art would have chosen a cellulosic paper when impermeability to bacteria and microorganisms is a concern, as taught by Brown et al.

7. Claims 7-9, 11, 27-29, 31, 42, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al (USPN 4,055,672) in view of Anderson et al (USPN 5,418,022).

Hirsch et al teach all that is claimed in claims 1, 6, 22, 26, 41, and teaches that the peelable film comprises a polyethylene film as shown above. Regarding claim 47, Hirsch et al also teach that the sheet form structural component is bonded

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at an edge region of said first layer to a non-porous panel to form therewith an enclosed interior volume for holding said product article (Figure 1 or 3), and teach that the second layer comprises a peelable polyethylene film (col.4, 1.56-65) and that the non-porous panel is formed of polyethylene film (col.3, 1.52-62).

Hirsch et al fail to teach that the first film is formed of a fibrous material of high-density polyethylene such as TYVEK. However, Hirsch et al teach that the first layer is formed of any gas permeable material having a suitable gas transmission rate of types which are well known in the art (col.4, 1.34-44). Anderson et al teach that well known permeable materials having a suitable gas transmission rate while remaining impermeable to bacteria and microorganisms, which would be a concern in food packaging, include fibrous layers specifically TYVEK (see abstract and col.2, 1.57-65). Anderson et al further teach that TYVEK is a spunbonded olefin sheet of high density polyethylene fibers formed by flash spinning continuous strands of ultrafine interconnected fibers, dispersing them onto a moving belt and then bonding them together with heat and pressure into a multi-layer sheet (col.1, 1.15-25). One of ordinary skill in the art would have recognized that Hirsch et al and Anderson et al are analogous art insofar as both references are concerned with

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using combinations of permeable and non-permeable layers to preserve easily contaminated products during storage and transportation of the products within the packages.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to substitute the TYVEK gas permeable layer of Anderson et al for the gas permeable layer of Hirsch et al because TYVEK is a well known material used in the formation of gas permeable layers within peelable packages, and one of ordinary skill in the art would have selected the appropriate gas permeable layer from well-known gas permeable layers depending on the intended end result of the product, as taught by Hirsch et al. Specifically, one of ordinary skill in the art would have chosen TYVEK when impermeability to bacteria and microorganisms is a concern, as taught by Anderson et al.

Regarding claims 48 and 49, Hirsch et al fails explicitly teach the bond strength between the first layer and the non-porous panel or the second layer. However, Hirsch et al teach that the first and second layers are adhesively joined in such a fashion that the second layer and the adhesive are peelable from the first layer in such a fashion that, upon peeling, an integral package comprising the tray having the inner permeable layer of the lid heat sealed thereto remains intact and allows

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the package contents to be exposed to the atmosphere (col.2, 1.56 - col.3, 1.9). One of ordinary skill in the art would have recognized that the seal strength between the first and second layer must be strong enough to remain sealed during transportation and storage of the article but weak enough to easily peel the second layer from the first layer and that the bond strength between the first layer and the non-porous panel must be substantially greater than the seal strength between first and second layer so that when the second layer is peel the first layer does not separate from the non-porous panel, as taught by Hirsch et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the bond and sealing strengths between the first layer and the second layer and non-porous panel respectively in the ranges taught in claims 48 and 49, because the requirements presented for the bond and seal strengths in Hirsch et al are the same requirements as the claimed invention. Thus, through routine experimentation one having ordinary skill in the art at the Applicant's invention was made would have arrived at the same ranges of bond and sealing strengths as the claimed invention, absent the showing of unexpected result.

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8. Claims 3-4 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (USPN 5,418,022) in view of Brown et al (USPN 4,055,672).

Anderson et al teach all that is claimed in claims 2 and 22 as shown above, but fail to teach using cellulosic paper as the gas permeable layer. However, Brown et al teach that it is notoriously well known in the art of packaging of medical supplies that are subjected to sterilizing gas while within the package to substitute paper for TYVEK as the gas permeable layer, depending on the intended end result of the product (col.5, 1.10-15). One of ordinary skill in the art would have recognized that TYVEK and paper are well known in the art as equivalent substitutes as a gas permeable layer, as taught by Brown et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made through routine experimentation to substitute paper for TYVEK as the gas permeable layer in the sterilizable package of Anderson et al, depending on the intended end result of the package, as taught by Brown et al.


Conclusion

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9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Weiss et al (USPN 6,251,489); Pettersson et al (USPN 6,065,597); Stockley, III et al (USPN 5,591,468); Horvath (USPN 4,461,420); Weiss et al (USPN 5,459,978).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

3/4/05

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Christopher P Bruenjes

Examiner

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CPB

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March 4, 2005